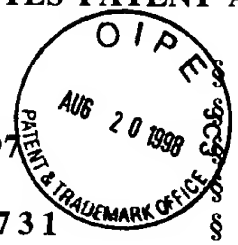
Attach # to 5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



APPLICANT: BROD	§	**ART UNIT: 1302**
FILED: April 21, 1997	§	
SERIAL NO.: 08/844,731	§	**EXAMINER: SAYALA, C**
FOR: METHODS OF TREATING AUTO-IMMUNE DISEASES USING TYPE ONE INTERFERONS	§	**DOCKET: D5716CIP3**

Box NON-FEE AMENDMENT
Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

DECLARATION UNDER 37 C.F.R. 1.132

JERRY S. WOLINSKY does hereby state as follows:

I am a Professor of Neurology at the University of Texas Health Science Center in Houston, Texas. I am skilled in the areas of autoimmune diseases generally and multiple sclerosis and diabetes in particular. My *curriculum vitae* is attached hereto. I have read U. S. patent application Serial No. 08/844,731, filed on April 21, 1997, and I am aware of the contents of, and responses to, the Office Actions, including all prior art cited against the '731 application.

The Applicant's invention claimed in the above-referenced application is specifically concerned with the oral administration and ingestion of interferons in a therapeutic application for treatment of

autoimmune diseases such as multiple sclerosis or diabetes. One of the major issues with respect to patentability of this application is: would it have been obvious to a person having ordinary skill in this art at the time the parent application was filed, i.e., April 1994, to orally administer interferon to treat autoimmune diseases in view of the **Cummins** (US Patent 5,019,382). For the reasons outlined *infra*, the answer is clearly no.

The experimental database relied upon in the **Cummins** patent is extremely limited. Whereas reasonable information is provided for the treatment of shipping fever in cattle, **Cummins'** additional claims regarding administration of interferons to treat viral and inflammatory disease are based on pure speculation or limited anecdotal data. It is my considered opinion that none of the supporting evidence in **Cummins** is in any way adequate to allow a reasonable physician, i.e., a person with ordinary skill in the art, with a reasonable expectation of being able to successfully utilize oral administration of interferon for the treatment of autoimmune diseases such as multiple sclerosis or diabetes.

In **Cummins**, two patients with rheumatoid arthritis and one patient with multiple sclerosis were given alpha interferon, administered orally. The art taught in the **Cummins** application stresses that administration of interferon should be directed at absorption through the oral mucosa, and not the gastric mucosa. Maximal contact with the oral or

pharyngeal mucosa is emphasized, contact with the gastric or intestinal mucosa is considered therapeutically nugatory.

In distinction to this, the instant invention clearly provides detailed experimental evidence regarding the role of ingested interferon in the treatment of inflammatory autoimmune diseases in experimental animals and humans. For example, in the animal models of human autoimmune disease, the interferon is delivered directly into the stomach or duodenum of the animal. In this experimental protocol, contact with the oral or pharyngeal mucosa is explicitly avoided. Convincing data that shows that delivery of the dose of oral interferon must be into the post-duodenal small intestine in order to be effective is presented; this specific route of administration is quite unlike the oral mucosa swish technique described by **Cummins**.

In Applicant's clinical studies with both normal human volunteers and patients with multiple sclerosis, the type one interferon dosage was "ingested". This very briefly exposed the oral/pharyngeal mucosa to the interferon, however no attempts at maximizing contact with the oral/pharyngeal mucosa were made, nor would there have been any significant absorption of the interferon through the oral or pharyngeal mucosa. Further, Applicant's invention provides valuable information regarding the limits of its application for expectations of therapeutic

benefits. Particularly important is Applicant's demonstration of an unusual dose-response relationship for oral administration of type one interferons to have any effect. It is meticulously demonstrated that both doses that are too low and doses that are too high lack any clinical benefit in animal models of human autoimmune disease, and it is concluded that similar restricted and unusual dose-response relationships are extant in man. Applicant's work thus defines a likely range of doses of type one oral interferons that would be clinically efficacious in humans with multiple sclerosis, diabetes and other autoimmune diseases.

Applicant additionally provides information that illustrate a range of orally administered interferon doses which provide measurable changes in biological response markers in both normal human volunteers and patients with multiple sclerosis. No similar data was presented by **Cummins** and doses suggested by **Cummins** did not include the range of doses expected by Applicant to be effective based on animal or human data. The critical dose range taught by Applicant is not obtainable based on **Cummins**' route and method of administration and dosage range presented. The effective dosage levels supported by Applicant's extensive findings exceed the highest doses taught by **Cummins**.

Gross et al., **Giron** et al., and **WO 94/20122. Gross** et al. reports use of alpha interferon (injected subcutaneously) for treatment of

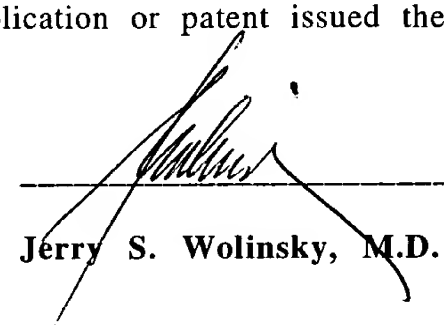
a condylomata acuminata in a diabetic individual. As the interferon was not used to treat diabetes, and no clinical improvement in the diabetes was reported, the germaneness of this abstract to the instant invention is dubious. **Giron** et al. discusses an antiviral effect of interferons in murine encephalomyocarditis. This viral condition is often accompanied by diabetes. The route of administration of the interferons is not mentioned nor are the types of interferons specified. The relevance of this citation to spontaneously occurring diabetes in humans and the NOD mouse model of human autoimmune diabetes is therefore doubtful. The reference **WO 94/20122**, is an abstract of a patent application delineating methods to treat "an asymptomatic preclinical autoimmune state in a mammal", or to inhibit "rejection of transplanted islet cells or a pancreas in a mammal". Again, the pertinence of this reference to the instant invention is unclear.

Clearly, one with ordinary skill in the art of autoimmune pathophysiology and treatment could not anticipate any therapeutic effects in humans from the oral administration of type one interferons after having read the **Cummins** and **Shibutani** et al., **Gross** et al., **Giron** et al., and the **WO 94/20122** references. One would expect such administration to have no clinical effect based on this route of administration. As is known, proteins are broken down in the gastrointestinal tract and hence ingested interferon protein should be digested without any therapeutic

consequences. Hence, a person with ordinary skill in this art would expect interferons to be biologically inert after being swallowed.

In conclusion, it is my opinion that the speculative and extremely limited anecdotal data presented in **Cummins** would in no way provide a person with ordinary skill in this art, e.g. a physician treating patients with autoimmune diseases such as multiple sclerosis or diabetes, with any prospect of being able to successfully treat such a disease via oral administration of type one interferons. Such a person could not have derived the approach detailed in the instant invention after having read the **Cummins** and **Shibutani** et al., **Gross** et al., **Giron** et al., **WO 94/20122** and **Sobel** references.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title I8 of the United States code, and that such willful false statements may jeopardize the validity of the application or patent issued thereon.



DATE 8-13-98

Jerry S. Wolinsky, M.D.

attach to #5

CURRICULUM VITAE

Jerry S. Wolinsky, M. D.

August 13, 1998

PRESENT TITLE

Professor of Neurology, The University of Texas - Houston, Health Science Center, School of Medicine, July, 1983-.
Member of Graduate Faculty, The University of Texas - Houston, Health Science Center, Graduate School of Biomedical Sciences, January, 1984-.

ADDRESS

The University of Texas - Houston, Health Science Center
Department of Neurology
6431 Fannin,
Houston, Texas 77030

phone: (713) 500-7048
fax: (713) 500-7041
email: jswolinsky@aol.com.

BIRTHDATE

November 26, 1943
Baltimore, Maryland.

CITIZENSHIP

USA

UNDERGRADUATE EDUCATION

1962 - 1965, Illinois Institute of Technology, Chicago, Illinois.

GRADUATE EDUCATION

1965 - 1969, University of Illinois College of Medicine, Chicago, Illinois.

POSTGRADUATE EDUCATION

June 1969 - July 1970, Rotating Internship: Mt. Zion Hospital and Medical Center, San Francisco, California.
July 1970 - June 1972, Resident in Neurology: University of California, San Francisco, California.
July 1972 - June 1973, Chief Resident in Neurology: University of California, San Francisco, California.
July 1973 - June 1975, Resident Clinical Associate in Neuropathology: Veterans Administration Hospital, San Francisco, California.

MILITARY SERVICE

December 1970 - September 1977, USA Reserve, Hamilton Reserve Center, California; Commander 147th Medical Detachment, Presidio of San Francisco, California, 1971-1974.

PAST ACADEMIC APPOINTMENTS

July 1973 - June 1975, Instructor in Neurology, University of California, San Francisco, California.
July 1975 - June 1978, Assistant Professor of Neurology, University of California, San Francisco, California.
July 1975 - June 1978, Research Associate, Veterans Administration Hospital, San Francisco, California.
June 1978 - June 1983, Associate Professor of Neurology, The Johns Hopkins University School of Medicine, Baltimore, Maryland.

July 1981 - June 1983, Associate Professor of Immunology and Infectious Diseases, The Johns Hopkins University School of Hygiene and Public Health, Baltimore, Maryland.

LICENSURE

Texas (G-4752) June 28, 1983 (current through 08-31-96).
Maryland (D-2219) July 20, 1978 (inactive after 1991).
California (G-20734) July 8, 1971 (inactive after 1987).

CERTIFICATION

National Board of Medical Examiners #105368, June 24, 1970.
American Board of Psychiatry and Neurology, May 1975.

CURRENT HOSPITAL AFFILIATIONS

Hermann Hospital, Neurology Active Staff.

PROFESSIONAL ORGANIZATIONS

American Academy of Neurology, 1971- (Fellow 1980).
American Academy for the Advancement of Science, 1973-, Fellow 1996-.
San Francisco Neurology Society, 1973-1978.
American Association of Neuropathologists, 1976-1989.
American Society for Microbiology, 1976-.
American Neurological Association, 1978-.
Maryland Neurological Society, 1978-1983.
Texas Medical Association, 1984-.
American Society for Clinical Investigation, 1984-.
American Society for Virology, 1984-.
Houston Neurological Society, 1984-.
Texas Neurological Society, 1985-.
Harris County Medical Society, 1986-.

CONSULTANTSHIPS

Carter Wallace, Inc., 1991-1992.
4-aminopyridine Multiple Sclerosis Treatment Trial Medical Advisory Group - Élan Pharmaceuticals Research Corporation, 1991-.
Multiple Sclerosis Treatment Medical Advisory Board - Sandoz Pharmaceticals, 1993-.
Consultant, Berlex Laboratories, 1993-.
Speakers Bureau, Health Science Communications, Inc., 1994-.
Advisory Board - Biogen, 1994-.
Clinical Advisory Committee - Viragen, Inc., 1994-.
Co-Chairman, Linomide Multicenter Trial Executive Committee, Pharmacia, 1994-.
Member, Independent Monitoring Board, Berlex Secondary Progressive Multiple Sclerosis Treatment Trial, 1995-.
Multiple Sclerosis Advisory Board, Zeneca Pharmaceuticals, 1995.
Multiple Sclerosis Consultant, Icos Corporation, 1995-.
MRI and Clinical Trials Consultant, TEVA Pharmaceuticals, 1995-.
Member, Data Safety Monitoring Board, Serono European and Canadian Relapsing-Remitting and Secondary Progressive Multiple Sclerosis Treatment Trials, 1995-.
Member, Organizing Committee, Steering Committee (Clinical and MRI Subcommittees) and Data Safety Monitoring Board, TEVA European and Canadian MRI Outcome Trial of Copolymer 1 in Relapsing-Remitting Multiple Sclerosis, 1995-.
Multiple Sclerosis Consultant, Boehringer Ingelheim, 1997.
Clinical Advisory Committee - Anergen, 1997-.
Multiple Sclerosis Consultant, Angiotech, 1998-.

Multiple Sclerosis Consultant, Astra, 1998-.

HONORS AND AWARDS

Phi Eta Sigma, 1963.
Alpha Omega Alpha, 1968.
David M. Olkon Scholarship, 1968-1969.
Basil O'Connor Starter Research Grant, The National Foundation March of Dimes, 1975-1978.
National Institutes of Health Research Career Development Award (1-K04-NS00443), 1979-1983.
University of Texas Medical School Dean's Teaching Excellence List, 1984-1985
University of Texas Medical School Dean's Teaching Excellence List, 1985-1986
University of Texas Medical School Dean's Teaching Excellence List, 1987-1988
University of Texas Medical School Dean's Teaching Excellence List, 1988-1989
University of Texas Medical School Dean's Teaching Excellence List, 1990-1991
University of Texas Graduate School of Biomedical Sciences Dean's Teaching Award, 1992-1993
University of Texas Medical School Dean's Teaching Excellence List, 1993-1994
The Best Doctors in America, Lucy Stec, editor, Woodward/White, Inc., 1992, 1994
American Men & Women of Science
Marquis *Who's Who in the South and Southwest* - 1995 and subsequent editions
International Who's Who in Medicine, Second Edition
Marquis *Who's Who in the World* - 1996
Marquis *Who's Who in Medicine and Health Care*, First Edition - 1997
The Best Doctors in America: Central Region 1996-1997, Steven W. Naifeh, editor, Woodward/White, Inc.
Fellow, American Academy for the Advancement of Science, 1996.
Co-chair, Multiple Sclerosis: Clinical Issues and Decisions, Summer Conference, San Francisco.
McEwan Visiting Professorship and Lecturer, University of Toronto, October 23-24, 1997.

COMMITTEES

Scientific Program Committee, American Academy of Neurology, 1979-1981.
Constitution Committee, American Association of Neuropathologists, 1978-1981.
Neurology Resident Selection Committee, Johns Hopkins Hospital, 1979-1982.
Awards Committee, American Association of Neuropathologists, 1981-1983.
National Multiple Sclerosis Society Working Group on Trials of New Drugs in MS, 1982-1986.
National Multiple Sclerosis Society Medical Advisory Committee on Trials of New Drugs in MS, 1986-1995; Chairman 1986-1989.
Medical Advisory Board, Southeast Texas Chapter Multiple Sclerosis Society, 1983-Chairman, 1986-1989.
University of Texas Medical School Biohazards Committee, 1983-1990; Chairman 1986-1990.
Medical Advisory Board, Southwest Regional Guillain-Barre Society, 1984-.
Ad Hoc Member National Institutes of Health Study Sections in Experimental Virology, Pathology A, Immunology A.
National Institutes of Health Site Visit Team Member NINCDS.
National Institutes of Health Special Review Committee Member NINDS.
National Multiple Sclerosis Society Working Group on Neuroimaging, 1985-1986.
University of Texas Medical School Self Study Subcommittee on Education, 1985.
National Institutes of Health Immunological Sciences Study Section Member, 1985-1989.
Southeast Texas Chapter Multiple Sclerosis Society, Board of Trustees, 1986-1989.
University of Texas Health Science Center Scientific Council, 1986-1990.
University of Texas Medical School Self Internal Review Committee on the Department of Internal Medicine, 1986-1987.
American Neurological Association Joint Advisory Committee of the Annals of Neurology, 1987-1993; Chairman 1991-1993.
National Multiple Sclerosis Society Clinics Committee, 1987-1991.
National Multiple Sclerosis Society Medical Advisory Board and Medical Advisory Board Executive Committee, 1988-2001.

Member at large, International Medical Advisory Board, International Federation of Multiple Sclerosis Societies, 1988-.
National Institutes of Health Reviewers Reserve, 1989-1993.
University of Texas Health Science Center Biohazards Committee, 1989-1992; Chairman 1986-1990.
University of Texas Health Science Center Faculty Development Leave Committee, 1989-1990.
University of Texas Medical School Faculty Development Leave Committee, Chairman 1989-1990.
University of Texas Medical School, Department of Neurology Residency Program Co-ordinator 1989-1990.
Program Director, Multiple Sclerosis Update 1989, Continuing Education Course of the University of Texas Medical School at Houston.
University of Texas Medical School Faculty Appointments, Promotions and Tenure Committee, 1990-1997.
Corresponding reviewer, Human Frontier Science Program 1990, 1991, 1992, 1994, 1996.
Member-at-large, University of Texas Medical School Research and Development Program (MSRDP) Committee, 1991-1993.
Measles Consultation Group, National Institute of Allergy and Infectious Diseases, Division of Microbiology and Infectious Diseases, 1991.
Abstract Reviewer and Chair Neurovirology III Session, American Academy of Neurology, 1991.
Program Director, Multiple Sclerosis Update Series 1991, Continuing Education Course of the University of Texas Medical School at Houston.
Abstract Reviewer and Chair CNS Infections Session, American Academy of Neurology, 1992.
Executive Committee for the Neuroscience Research Center, University of Texas Health Science Center at Houston, 1992-1997.
National Institutes of Health Special Emphasis Review Panel Member NINCDS, 1992.
National Multiple Sclerosis Society Scientific Peer Review Committee "B", 1993-1998.
National Institutes of Neurological Disorders and Stroke, Board of Scientific Counselors, Ad Hoc Member, 1992.
University of Texas Medical School Internal Review Committee on the Department of Neurobiology and Anatomy, 1992-1993.
Member, Scientific Advisory Committee, The University of Texas Clinical Research Center at Hermann Hospital, 1993-; Chair 1996-.
Co-Program Director, Multiple Sclerosis Update Series 1993, Continuing Education Course of the University of Texas Medical School at Houston.
Annual Meeting Plenary Program Committee, American Neurological Association, 1993-1995.
University of Texas Health Science Center Scientific Review Committee, 1994-.
Chairman, University of Texas Medical School, Internal Review Committee on the Department of Internal Medicine, 1995.
Co-Program Director, Multiple Sclerosis Update 1995, Continuing Education Course of the University of Texas Medical School at Houston.
Steering Committee and Program Committee, Americas Committee for Trial and Research in Multiple Sclerosis, 1996-.
Member, International Working Party on the Use of Magnetic Resonance in Multiple Sclerosis, 1997-.

EDITORIAL POSITIONS

Editorial Board, Annals of Neurology, 1980-1987.
Editorial Advisory Board, Critical Reviews in Clinical Neurobiology, 1983-1988.
Editorial Board, Multiple Sclerosis: Clinical and Laboratory Research, 1994-.
Editorial Board, Journal of Neurovirology, 1994-1996.
Associate Editor, Scientific American Medicine, 1995-.

Frequent Ad Hoc Reviews for Annals of Neurology, Archives of Neurology, Archives of Virology, Clinical Microbiology Reviews, Journal of General Virology, Journal of Infectious Diseases, Journal of Neuroimmunology, Journal of Neuropathogy and Experimental Neurology, Journal of Virology, Mayo Clinic Proceedings, Neurology, New England Journal of Medicine, Science, Southern Medical Journal, Virology, Virology Research.

SPONSORSHIP OF SUMMER STUDENTS

Fawn Lewis, MSIII - 1990

Jean-Paul Wolinsky, undergraduate - 1991, 1992, 1993
Eve Rogers, MSII, 1993

SPONSORSHIP OF PRE-DOCTORAL FELLOWS

Joyce A. Kobori, M.D. - June 1977 - May 1978, Special Pre-doctoral Fellow National Multiple Sclerosis Society, Role of Subviral Particles in Disease Pathogenesis - Currently, Assistant Professor of Pediatrics and Molecular Genetics, Stanford University.

SPONSORSHIP OF GRADUATE DEGREE CANDIDATES

M. Neal Waxham, Ph.D., - September 1980 - May 1984, Ph.D. candidate, Immunology and Infectious Disease, Johns Hopkins University School of Hygiene and Public Health, Molecular Mechanisms of Rubella Virus Pathogenesis. - Currently, Associate Professor of Neurobiology and Anatomy, The University of Texas Health Science Center at Houston.

Amy Lovett, Ph.D. - June 1989 - May 1993, Ph.D. candidate, Program in Virology, Graduate School of Biomedical Sciences, The University of Texas - Houston, Health Science Center. Molecular Immune Determinants of Rubella Virus. - Currently, Post-doctoral Fellow, Neuroimmunology, Washington University, St. Louis.

Stephanie Edson, M.S. - June 1991 - August 1994, M.S. candidate, Program in Virology, Graduate School of Biomedical Sciences, The University of Texas - Health Science Center. Immunogenicity of a Prototype Chimeric Peptide Rubella Vaccine.

SPONSORSHIP OF POST-DOCTORAL FELLOWS

John B. Penney, Jr., M.D., July 1977 - June 1978, Veterans Administration Post-doctoral Fellow, Ultrastructure of Theiler's Virus Encephalitis - Currently, Professor of Neurology, Harvard Medical School.

Irma M. Parhad, M.D., June 1977 - July 1978, National Institutes of Health Post-doctoral Fellow, Ultrastructure of Measles Virus Infection - Currently, Assistant Professor of Neurology, Calgary University (*deceased*).

Micheline McCarthy, Ph.D., July 1978 - June 1980, National Institutes of Health Post-doctoral Fellow, Molecular Biology of Mumps Virus - Currently, Assistant Professor of Neurology, The University of Miami.

Patricia K. Coyle, M.D., July 1978 - June 1980, National Institutes of Health Post-doctoral Fellow, Immune Complexes in CNS Diseases - Currently, Professor of Neurology, The State University of New York (Stony Brook).

Alan Seay, M.D., July 1979 - June 1981, National Institutes of Health Teacher Investigator Awardee, Ross River Virus Encephalitis Demyelination - Currently, Associate Professor of Neurology and Pediatrics, The University of Colorado Heath Science Center.

Alfred C. Server, M.D., Ph.D., July 1979 - June 1981, National Institutes of Health Post-doctoral Fellow, Immunochemical Characterization of Mumps Virus - Currently, Law Student, Harvard, Boston.

David C. Merz, M.D., Ph.D., January 1981 - June 1983, Special Post-doctoral Fellow, American Cancer Society, Molecular Aspects of Mumps Virus Pathogenesis - Currently, Assistant Professor of Medicine, Rochester University.

Betty Slagle, Ph.D., April 1985 - October 1986, Post-doctoral Fellow, National Multiple Sclerosis Society, Rubella Virus Receptor Interactions - Currently, Assistant Professor, Department of Virology, Baylor College of Medicine.

Avindra Nath, M.D., May 1986 - December 1988, Post-doctoral Fellow, Anti-idiotype Antibodies to the Rubella Virus Receptor - Currently, Associate Professor, Department of Neurology, The University of Kentucky Health Science Center.

Rui Jin, M.D., April 1989 - July 1991, Post-doctoral Fellow, Molecular Neuroimmunology of Rubella Virus Epitopes and Proteolipid Protein Gene Alleles - Currently, Research Associate, Department of Neurology, The University of Texas Health Science Center at Houston.

GRADUATE STUDIES SUPERVISORY COMMITTEES

Lovely K. Fotedar, MS, In vivo Proton Magnetic Resonance Spectroscopy of Stress-induced Water Changes in Human Gastrocnemius Muscle.

Paul Kussie, PhD, Molecular Structure of Antibodies Against Small Ligands.

James C. Falconer, PhD, Quanitative MRI of Spinal Cord Injury: Correlative Studies.

Barry J. Bedell, PhD, Automatic Quantitation of Multiple Sclerosis Lesions on MR Images.
David Fenyes, MD/PhD, To be defined (Februray 1994 -).
Nicholas Zacharopoulos, MS, MR diffusion tensor imaging of normal human brain with selective tissue suppression.

CURRENT GRANTS

PRINCIPAL INVESTIGATOR

Clayton Foundation for Research: Viral mimicry and multiple sclerosis, 1/01/93-12/31/98, total direct costs awarded to date: $751,587; current year $141,792.

TEVA Pharmaceuticals: Preclinical studies of copolymer 1; 10/01/96-09/30/1999; total direct costs projected: $177,224.

TEVA Marion Partners: Protocol 01-9004, Open label study to evaluate the safety of Copaxone® and to monitor the neurologic course of disease in multiple sclerosis patients treated with Copaxone®: MRI Analysis Center; 04/01/98-10/15/99; total direct costs: $166,012.

ICOS Corporation: Clinical study protocol A960002i, phase 2 study of Hu23F2G in acute exacerbations of multiple sclerosis; 12/01/96-10/31/98; total direct costs projected: $319,328.

ICOS Corporation: Clinical study protocol AMS05, phase 2 study of Hu23F2G in acute exacerbations of multiple sclerosis: MRI Analysis Center; 04/01/98-03/31/99; total direct costs projected: $158,358.

Biogen: Protocol C97-830: A randomized, double-blind, placebo-controlled study to evaluate the efficacy of Avonex® in the treatment of secondary progressive multiple sclerosis; 06/01/98-05/31/01; total direct costs projected: $177,224.

Angiotech Pharmaceuticals: Clinical protocol 002-MPMS98-1, Micellar Paclitaxel for the treatment of secondary progressive multiple sclerosis: MRI Analysis Center; 07/21/98-06/30/00; total direct costs projected: $105,641.

Biogen: CombiRx study of relapsing multiple sclerosis: MRI Analysis Center; 10/01/98-09/31/99; total direct costs projected: $61,157.

CO-INVESTIGATOR

National Institutes of Health: Serial spectroscopy and imaging of multiple sclerosis (RO1-NS31499), 04/01/93-03/31/02, total direct costs awarded: $1,959,461; Dr. Ponnada A. Narayana is the principal investigator.

National Institutes of Health: Oral IFN-α: Biological effects in relapsing-remitting multiple sclerosis (RO1-NS35619), 04/01/97-03/31/99, total direct costs awarded: $584,884; Dr. Staley A. Brod is the principal investigator.

TEVA Pharmaceuticals: Open label study to evaluate the safety of Copaxone® and to monitor the neurologic course of disease in multiple sclerosis patients treated with Copaxone®; 04/01/98-03/31/00; total direct costs projected: $104,490 (subcontract through University of Maryland); Dr. J. William Lindsey is the principal investigator.

PREVIOUS GRANTS

PRINCIPAL INVESTIGATOR

VAH Career Development Award-Research Associate: Pathogenesis of Viral Related Diseases (RA-793), 7/75-6/78.

National Foundation - March of Dimes: Basil O'Connor Starter Research Grant: Pathogenesis of the Late Onset Progressive Rubella Panencephalitis Syndrome (5-63), 9/75-6/78.

VAH-BIS: Pathogenesis of Viral Related CNS Diseases (MRIS 9510), 7/76-6/78.

National Foundation - March of Dimes: Effects of Rubella Virus on Neural Tissues (1-642), 7/78-6/80.

National Institutes of Health: Neurovirulence and Persistence of Mumps Virus (1 RO1-A115721), 5/79-4/82.

United Cerebral Palsy Research and Educational Foundation: Pathogenesis of the Cerebral Palsy of Rubella Virus (R-319-84), 2/81-1/84.

United Cerebral Palsy Research and Educational Foundation: Pathogenesis of the Cerebral Palsy of Rubella Virus (R-319-84), 2/84-7/86, total direct costs awarded: $105,166.

National Institutes of Health: Immunoglobulin Access to Neoantigens on CNS Cells. (1 RO1 NS20352-01), 12/83-4/87, total direct costs awarded: $265,250.

National Multiple Sclerosis Society: Characterization of the Rubella Virus Receptor (RG 1855-A-1), 4/86-10/89, total direct costs awarded: $251,940.

National Multiple Sclerosis Society: MRI Techniques to Study the Stages of Disease Activity (PP0064), 9/88-12/89, total direct costs awarded: $19,029.

Sandoz Inc.: A Double-blind Multicenter Clinical Trial to Assess the Safety and Efficacy of Cyclosporine in the Treatment of Multiple Sclerosis, 1/85-12/90, total direct costs awarded: $88,694.

National Multiple Sclerosis Society: Non-lethal Mutations in PLP and Multiple Sclerosis (PP0162), 08/01/90-07/31/91; total direct costs awarded: $18,517.

Merck Sharp and Dohme: PCR Amplification of the Rubella Genome for Detection of Vaccine Persistence in Man, 8/01/89-04/30/93, total direct costs awarded: $68,000.

National Institutes of Health: Molecular Immune Response Determinants of Rubella Virus (RO1 AI26943), 6/01/89-12/31/94, total direct costs awarded: $792,050.

TEVA Pharmaceuticals: Copolymer I Therapy of Relapsing Multiple Sclerosis; 10/01/91-01/31/95; total direct costs: $102,384 (subcontract through University of Maryland).

Athena Neurosciences: A multicenter, double-blind, randomized, placebo-controlled study to assess the efficacy and safety of Tizanidine and the relationship of plasma concentrations to the changes in muscle tone and common adverse events; 08/01/94-07/31/95; total direct costs: $63,938.

Élan Pharmaceuticals Research Corporation: A Randomized, double-blind, placebo-controlled, titration study of Fampridine SR® administered BID to patients with multiple sclerosis; 09/01/94-08/31/95; total direct costs: $53,911.

National Multiple Sclerosis Society: Does the CD3ϵ gene differ in multiple sclerosis; 02/01/95-1/31/96; total direct costs: $18,750.

Athena Neurosciences: A multicenter, open-label, long-term study to evaluate the safety of Tizanidine tablets in patients suffering from spasticity due to multiple sclerosis; 08/01/94-07/31/97; total direct costs projected: $82,043.

Pharmacia: Magnetic resonance imaging analysis center for: A randomized, double-blind, placebo-controlled, phase 3 study of roquinimex (Linomide®) in secondary progressive multiple sclerosis; 08/01/95-04/01/98; total direct costs: $1,135,962.

TEVA Pharmaceuticals: Open label study to evaluate the safety of Copaxone® and to monitor the neurologic course of disease in multiple sclerosis patients treated with Copaxone®; 08/12/94-03/31/98; total direct costs projected: $148,706 (subcontract through University of Maryland).

CO-INVESTIGATOR

NINCDS: Virology-Immunology-Pathology of Neurological (T32-NS07073), 7/76-6/78.

United Cerebral Palsy Research and Educational Foundation: Effects of Perinatal Infections on the Developing Nervous System (R-230-76), 1/80-12/81.

NINCDS: Neurovirology and Immunology Training Grant (TS NS07000), 7/80-6/83.

NINCDS: Cellular Dysfunction Neurological Diseases (NS-15721-02) 1/81-12/83.

NINCDS: Plasmapheresis of Acute Guillain-Barre (NS17053) 12/80-11/83.

NIAID: Herpes Simplex Encephalitis Collaborative Study (AI-12667-UAB-82).

National Multiple Sclerosis Society: Magnetic Resonance Imaging in Chronic Progressive Multiple Sclerosis, 4/86-3/89 (co-investigator with Donald Paty, M.D.), total direct costs awarded: $176,388.

Retinitis Pigmentosa Foundation: The Role of Rubella Virus in Retinitis Pigmentosa, 7/89-6/90; subcontract through Dr. Lowell L. Williams, Ohio State University, total direct costs awarded subcontract: $27,436.

National Institutes of Health: Purchase of a Laser Desorption/TOF Mass Spectrometer; total direct costs awarded $315,000; Dr. R.M. Caprioli was the principal investigator of this BRS shared instrumentation grant.

National Multiple Sclerosis Society: Proton Magnetic Resonance Spectroscopy and Imaging of Multiple Sclerosis (RG 2236-A-1), 10/01/90-09/30/92, total direct costs awarded: $140,246; Dr. Ponnada A. Narayana was the principal investigator.

National Multiple Sclerosis Society: Spectroscopy and Imaging of Multiple Sclerosis (RG 2236-B-2), 10/01/92-09/30/95, total direct costs awarded: $319,624; Replaced by NIH award effective 04/01/93; Dr. Ponnada A. Narayana was the principal investigator.

Texas Higher Education Coordinating Board Advanced Research Program: Development of Advanced Magnetic Resonance Technology for the in vivo Evaluation of Neurologic Diseases (0116118072), 11/01/91-

10/31/93, total direct costs awarded $128,211; Dr. Ponnada A. Narayana was the principal investigator.

Neurocrine Biosciences: Double-blind, randomized, placebo-controlled evaluation of the safety, tolerability and pharmokinetics of nbi-577 in patients with multiple sclerosis, protocol 01; 09/01/96-08/31/98; total direct costs: $137,000; Dr. J. William Lindsey was the principal investigator.

Pharmacia: A randomized, double-blind, placebo-controlled, phase 3 study of roquinimex (Linomide®) in secondary progressive multiple sclerosis; 10/01/95-12/31/97; total direct costs: $265,000; Dr. J. William Lindsey is the principal investigator

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